IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.:	10/509,416	Conf. No.:	1931
Inventor:	Josef Lauter		
Filed:	September 24, 2004		
TC/AU:	3766		
Examiner:	Jonathan Thomas		
Docket No.:	DE020075US (PHB-10-6462)		
Customer No.:	24737		

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

AMENDED APPEAL BRIEF

Dear Sir:

In response to the Notification of Non-Compliant Appeal Brief mailed on October 2, 2008, attached herewith is an amended Appeal Brief.

TABLE OF CONTENTS

I. REAL PARTY IN INTEREST

The real party in interest in the above-entitled application is Koninklijke Philips Electronics N.V., Eindhoven, NL.

II. RELATED APPEALS AND INTERFERENCES

The undersigned attorney/agent, the appellants, and the assignee are not aware of any related appeals or interferences that would directly affect, or be directly affected by, or have a bearing on the Board's decision in this pending appeal.

III. STATUS OF THE CLAIMS

Claims 1-10 are rejected, and are all on appeal. Claims 11-20 have been withdrawn from consideration.

IV. STATUS OF AMENDMENTS

An after final amendment submitted on June 11, 2008 has not been entered.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

Independent **claim 1** is directed towards a wearable heart monitoring system for monitoring of a cardiac arrhythmia. The system includes ECG sensors configured to obtain patient heart data and conditioning and interpreting circuitry that processes the heart data. The conditioning and interpreting circuitry comprises a real-time evaluator that measures and analyzes a histogram of a temporal distribution of an interval between successive corresponding peaks in an ECG spectrum during a plurality of successive heart cycles and an alarm generator that generates an alarm based on the analysis of the histogram. (*See, inter alia,* page 1, lines 28-29 to page 2, lines 1-4; page 3, lines 32-34 to page 4, lines 1-9; page 4, lines 18-35; and Figures 2-4).

Claim 2, which depends from claim 1, recites that the system further comprises an RF-link that transmits a further alarm to a remote monitoring station. (*See, inter alia,* page 2, lines 15-21).

Claim 3, which depends from claim 1, recites that ECG sensors are housed on an elastic belt. (*See, inter alia,* page 3, lines 32-34 to page 4, lines 1-17; page 5, lines 25-34 to page 6, lines 1-6; and Figures 1 and 4)

Claim 4, which depends from claim 3, recites electrical wiring for arranging electrical connections of the monitoring system. (*See, inter alia,* page 6, lines 2-5; and Figures 1 and 4).

Claim 5, which depends from claim 4, recites a wire material has a substantially a same elasticity as a material constituting the elastic belt. (*See, inter alia,* page 2, line 30 to page 3, lines 1-4).

Claim 6, which depends from claim 5, recites the system comprises at least two electrodes. (*See, inter alia,* page 4, lines 11-13; and Figures 1 and 2).

Claim 7, which depends from claim 1, recites the system further comprises a motion sensor. (*See, inter alia,* page 3, lines 6-10; and page 4, lines 11-14).

Independent **claim 8** is directed towards a method for alerting a patient for a substantial probability of a cardiac arrest event, the method being based on results of continuous monitoring of a cardiac activity by means of a cardiac monitoring system comprising a set of electrodes, a conditioning and interpreting circuitry and alarm, and a generator. The method includes: performing a continuous acquisition of data related to the cardiac activity with the electrodes; processing the data for extracting a characteristic

parameter with the conditioning and interpreting circuitry, wherein the conditioning and interpreting circuitry is located on a physiological sensing belt in operative communication with the patient; performing a classification of the extracted characteristic parameter; and generating an alarm with the alarm generator when the characteristic parameters falls within an alarm-relevant category. (*See, inter alia,* page 3, lines 11-17; and page 4, lines 18-34; and Figure 2)

Claim 9, which depends from claim 8, recites an alarm with a high priority is generated in case of a sudden cardiac arrest. (*See, inter alia,* page 2, lines 7-11; page 4, lines 7-9; page 4, lines 29-34; and Figure 2).

Claim 10, which depends from claim 8, recites the alarm generator is located on the belt. (*See, inter alia,* page 1, lines 1-9; and page 4, lines 7-9).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claim 9 is indefinite under 35 U.S.C. 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which appellant regards as the invention.

Whether claims 1-10 are unpatentable over 35 U.S.C. 103(a) over Golasarsky (US 5,891,044) in view of Segalowitz (US 5,307,818).

VII. ARGUMENTS

A. The Rejection of Claim 9 under 35 U.S.C. 112

Claim 9 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which appellant regards

as the invention. Particularly, the Office asserts it is unclear what constitutes a high priority alarm and what prior art elements do or do not fall within the bounds of this limitation. However, appellant disagrees because a person of ordinary skill in the art would know what a alarm of a high priority is, e.g., an alarm that signals an event such as cardiac arrest having great urgency associated with it as compared to an alarm that signals an event of lesser urgency. Accordingly, the rejection of claim 9 should be reversed.

B. The Rejection of Claims 1-10 under 35 U.S.C. 103(a)

Claims 1-10 stand rejected under 35 U.S.C. 103(a) over Golasarsky in view of Segalowitz. This rejection should be reversed because Golasarsky in view of Segalowitz does not teach or suggest all of the limitations of the subject claims and, therefore, fails to establish a *prima facie* case of obviousness with respect to the subject claims.

> To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F 2d 981, (CCPA 1974). MPEP §2143.03

Claims 1-7

Independent **claim 1** is directed towards a wearable heart monitoring system for monitoring of a cardiac arrhythmia. The wearable heart monitoring system includes, *inter alia*, a real-time evaluator that measures and analyzes a histogram of a temporal distribution of an interval between successive corresponding characteristic peaks in an ECG spectrum during a plurality of successive heart cycles, and an alarm generator that generates an alarm based on the analysis of the histogram. The Office contends that these claim aspects would have been obvious to one of ordinary skill in the art based upon Golasarsky in view of Segalowitz. However, the combination of Golasarsky in view of Segalowitz does not teach or suggest such claim aspects.

Golasarsky teaches an apparatus and method for determining a user's stress state and/or a distress condition. The apparatus for use with the method is disclosed in col. 8, lines 4-20, as a module strapped to the user's wrist comprising a passive SOS time interval sensor, a radio means for conveying recorded time intervals, a motion sensor, means responsive to the motion sensor to distinguish a physical state of the user, a galvanic skin sensor, and a means responsive to the galvanic skin sensor to distinguish between states of connectivity. The stress state and/or distress condition is detected from simple parameters derived from the recording of a plurality of durations of successive Time Intervals between the Start of Systole (SOS)(measured in pressure) to the Start of Systole in successive heart beats (see Fig. 1B). The Time Intervals are detected by the SOS time interval sensor 80 (see Figs. 3 and 5).

Segalowitz discloses a method and system for electrocardiographic monitoring. In an embodiment, the system comprises a precordial strip assembly having six conductive elements V_1- V_6 (see Figures 8 and 10a). The precordial strip is placed over the precordium of a patient so that the conductive elements can detect electrical signals generated when the heart muscle contracts. The method and system in the various disclosed embodiments also includes other conductive elements for connection to the skin of the patient on selected parts of the patient's body. For example, in Figures 1, 8, and 9 there are additional conductive elements connected to one or more of the left arm, right arm, right leg and left leg of a patient. In Figures 17, 18, 22 and 23, disclosed is a precordial strip having the six conductive elements V_1- V_6 and the additional conductive elements for connection to the precordium of a patient. The additional conductive elements correspond to the traditional precordial limb detection points necessary for measuring ECG signals. In Figures 25 and 26, disclosed is a precordial strip having the six conductive elements V_1- V_6 and the additional conductive elements located in proximity thereto for connection to the precordium of a patient. The conductive elements V_1- V_6 and the additional conductive elements are connected to suitable electrocardiograph (ECG) equipment which records the electrical signals.

The Office concludes that it would have been obvious to one of ordinary skill in the art to add the electrodes V_1- V_6 of Segalowitz to the watchband of Golasarsky in order to

acquire ECG data as suggested in Golasarsky. However, applicant respectfully traverses this conclusion.

In this regard, if the conductive elements V_1- V_6 of Segalowitz were to be added to the watchband in Golasarsky as the Office has proposed, the conductive elements V_1- V_6 of Segalowitz could not obtain patient heart data (via ECG sensors) as is required by claim 1. In order to acquire the patient heart data, the conductive elements V_1- V_6 must contact the skin of the patient in a location suitable to detect heart signals. One such location has been found to be the patient's precordium. The additional conductive elements must also be in contact with the patient's skin at other selected points on the patient's body. In Segalowitz, the precordial strip having the six conductive elements V_1- V_6 is placed over the precordium of the patient for this reason. If the conductive elements V_1- V_6 of Segalowitz were to be added to the wrist module of Golasarsky, the conductive elements V_1- V_6 would not be positioned on the patient in a location suitable to obtain the required patient heart data. The patient's wrist is not a suitable location to detect heart signals.

Moreover, Golasarsky does not teach or suggest acquiring patient heart data as the Office contends (col. 2, lines 39-55). As previously discussed, Golasarsky discloses detecting a user's stress state with a SOS time interval sensor 80 positioned in a module strapped to the user's wrist. The SOS time interval sensor 80 senses changes in pressure between Time Intervals in successive heart beats. The Time Interval data is not the same as ECG data. Accordingly, the rejection of claim 1 should be reversed.

Claims 2-7 depend from claim 1 and the rejection thereof should be reversed at least by virtue of their dependency upon an allowable base claim.

Claims 8-10

Independent **claim 8** is directed towards a method for alerting a patient for a substantial probability of a cardiac arrest event for use with an apparatus substantially as claimed in claim 1. As such, the discussion above regarding claim 1 applies *mutatis mutandis* to claim 8, and this rejection should be reversed.

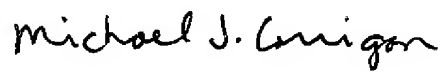
Claims **9-10** depend from claim 8 and the rejection thereof should be reversed at least by virtue of their dependency upon an allowable base claim.

CONCLUSION

In view of the foregoing, it is submitted that the claims distinguish patentably and non-obviously over the prior art of record, and reversal of the rejection of the claims herein is respectfully requested.

Respectfully submitted,

Driggs, Hogg, Daugherty & Del Zoppo Co., L.P.A.



Michael J. Corrigan, Reg. No. 42,440
Anthony M. Del Zoppo, III Reg. No. 51,606
Driggs, Hogg, Daugherty & Del Zoppo Co., L.P.A.
38500 Chardon Road
Willoughby Hills, Ohio 44094
Phone: 1.440.391 5100
Fax: 1.440.391.5101

Direct all correspondence to:
Yan Glickberg, Reg. No. 51,742
Philips IP&S
595 Miner Road
Cleveland, Ohio 44143
Phone: (440) 483-3455
Fax: (914) 332-0615

VIII. CLAIM APPENDIX

1. A wearable heart monitoring system for monitoring of a cardiac arrhythmia, said system comprising:

ECG sensors configured to obtain patient heart data,

a conditioning and interpreting circuitry that processes the heart data, the conditioning and interpreting circuitry comprising:

a real-time evaluator that measures and analyzes a histogram of a temporal distribution of an interval between successive corresponding characteristic peaks in an ECG spectrum during a plurality of successive heart cycles; and

an alarm generator that generates an alarm based on the analysis of said histogram

2. The system according to claim 1, further comprising an RF-link that transmits a further alarm to a remote monitoring station.

3. The system according to claim 1, wherein the ECG sensors are housed on an elastic belt.

4. The system according to claim 3 further comprising electrical wiring for arranging electrical connections of the monitoring system, said wiring being integrated in the belt.

5. The system according to claim 4, wherein a wire material has substantially a same elasticity as a material constituting the elastic belt.

6. The system according to claim 5, wherein said system comprises at least two electrodes.

7. The monitoring system according to claim 1, wherein said system further comprises a motion sensor.

8. A method for alerting a patient for a substantial probability of a cardiac arrest event, said method being based on results of continuous monitoring of a cardiac activity by means of a cardiac monitoring system comprising a set of electrodes, a conditioning and interpreting circuitry and alarm, generator, said method comprising:

performing a continuous acquisition of data related to the cardiac activity with the electrodes;

processing the data for extracting a characteristic parameter with the conditioning and interpreting circuitry, wherein the conditioning and interpreting circuitry is located on a physiological sensing belt in operative communication with the patient;

performing a classification of the extracted characteristic parameter;

generating an alarm with the alarm generator when the characteristic parameters falls within an alarm-relevant category.

9. The method according to claim 8, wherein an alarm with a high priority is generated in case of a sudden cardiac arrest.

10. The method according to claim 8, wherein the alarm generator is located on the belt

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None known to undersigned attorney/agent.